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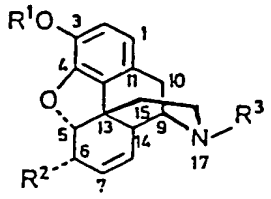
ART 34 AMDT

Rec'd on 16 MAR 00

CLAIMS

1. A substance consisting substantially of the acid addition salt of a morphine alkaloid and an organic acid, said morphine alkaloid having the following Formula I:



(I)

where R^1 is selected from the group consisting of H, C_1- to C_6-alkyl residues, preferably methyl, ethyl-, propyl, i-propyl, $C(O)CH_3$; R^2 is selected from the group consisting of the monad residues H, OH, $OC(O)CH_3$, whereby in this case the fourth valence of the (6)-C atom is occupied by H, or the dyad residues =O, $=CH_2$; R^3 is selected from the group consisting of $-CH_3$, cyclopropyl, cyclobutyl and allyl; and where

- the bond at C7/C8 may be saturated, or a nitroxyl group may be present at N_{17},

characterized in that the organic acid is selected from

- monoesters of C_3- to C_{16}-dicarboxylic acids with monohydric C_1- to C_4-alcohols, especially methanol,

- C_2- to C_{16}-sulfonic acids,

- substituted benzoic acids, s l cted from the group of halogen, hydroxy, alkyl, hydroxyalkyl, alkoxyalkyl and/or alkoxy-substituted benzoic acids, as well as of the aminosubstituted benzoic acids, which may optionally be alkylated at the N atom,

- substituted or non-substituted 5-ring or 6-ring heterocycles comprising at least one N or S atom and having a carboxyl group function, especially a carboxy, carboxymethyl, carboxyethyl or the - optionally branched - carboxypropyl or carboxybutyl groups as substituents,

- saturated or unsaturated, optionally substituted, oxocarboxylic acids having 5 to 10 C atoms,

- phenyl-substituted or phenoxy-substituted saturated C_2- to C_4-carboxylic acids,

- aliphatic, aromatic or heterocylic C_2- to C_{12}-amino acids, wherein one amino group is substituted with an - optionally substituted - C_2- to C_6-alkanoyl group or an - optionally substituted - benzoyl group.

2. Substance according to Claim 1, wherein the organic acid is selected from aliphatic monoaminomonocarboxylic acids, wherein the amino group is substituted with a C_2- to C_6-alkanoyl group, which may be mono- or polysubstituted with hydroxy, C_1- to C_4-alkoxy- or C_1- to C_4-hydroxyalkyl, or wherein the amino group is substituted with the benzoyl residue, which may be mono- or polysubstituted with C_1- to C_4-alkyl, C_1- to C_4-alkoxy, C_1- to C_4-hydroxyalkyl, halogen, amino or hydroxy.

3. Substance according to Claim 2, wher in the organic acid is selected from aliphatic C_2- to C_6-monoamino-monocarboxylic acids, wherein the amino group is substituted with the acetyl group or the benzoyl group.

4. Substance according to Claim 1, wherein the organic acid is selected from:

- hydroxy-(C_1- to C_4)-alkyl, C_1- to C_6-alkoxy-(C_1- to C_4)-alkyl-substituted or p- or m-hydroxy-substituted benzoic acids,
- monoesters of C_5- to C_{10}-dicarboxylic acids, especially suberic acid, azelaic acid and sebacic acid,
- C_4- to C_8-sulfonic acids, especially hexanesulfonic acid.

5. Substance according to Claim 1, characterized in that the acid is selected from C_1- to C_4-alkyl-substituted benzoic acids, preferably C_1- to C_4-trialkyl-substituted benzoic acids.

6. Substance according to Claim 1, characterized in that the organic acid is hexanesulfonic acid, aminobenzoic acid or trimethylbenzoic acid.

7. Substance according to Claim 1, characterized in that the 5-ring or 6-ring heterocycle is a pyridine-carboxylic acid, preferably nicotinic acid or lipoic acid.

8. Substance according to Claim 1, characterized in that the oxocarboxylic acid is a 2-, 4-, 5- or 9-oxocarboxylic acid which is optionally unsaturated.

9. Substance according to Claim 8, characterized in that th oxocarboxylic acid is 5-oxopyrrolidine-2-carboxylic acid, levulic acid or oxodec-2-ene acid.

10. Substance according to Claim 3, characterized in that the organic acid is acetylglycin or hippuric acid.

11. Substance according to any one of the preceding Claims, characterized in that the morphine alkaloid is morphine, codeine, heroin, ethylmorphine, levorphanol or hydromorphone.

12. A composition containing at least one substance according to Claims 1 to 11.

13. Composition according to Claim 12, characterized in that the composition comprises a solution or suspension of the substance in glycerin, ethylene glykol, dimethyl isosorbide, oleic acid and/or dimethyl sulfoxide.

14. Method for the production of the substance according to any one of Claims 1 to 11, comprising the steps of providing a solution of the morphine alkaloid, reacting, in a further step, said solution with equimolar amounts of a solution of the organic acid and isolating the resultant addition salt.

15. Preparation for transdermal or transmucosal administration, comprising the substance according to any one of the Claims 1 to 11 or the composition according to Claim 12 or 13.

16. Preparation according to Claim 15 for pain control or for use in the withdrawal therapy of drug addicts.

17. Preparation according to Claim 15 or 16, wh reby said preparation is a lotion, ointment, creme, gel or spray, an iontophoretic device, a transmucosal therapeutic system or a transdermal therapeutic system (TTS), comprising a backing layer, which optionally is active substance-impermeable, and a reservoir layer.